

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

**CAVALERI et al.**

**Serial No.: Not yet assigned**

Filed: Submitted herewith

For: STABLE PHARMACEUTICAL  
COMPOSITIONS OF  
DALBAVANCIN AND METHODS  
OF ADMINISTRATION

Group Art Unit: Not yet assigned

INFORMATION DISCLOSURE STATEMENT

MAIL STOP PATENT APPLICATION

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97–1.98, information relating to the above–identified application is hereby disclosed. The accompanying Form PTO–1449 provides a listing of documents that may be relevant to the subject application.

It is requested that the Examiner fully consider the art cited in the accompanying Form 1449, initial the left–most column of the form adjacent each cited reference, and return a copy for Applicants' records. It is further requested that the art be cited on the cover of any patent issuing from the subject application.

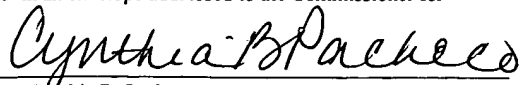
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CERTIFICATE OF MAILING (37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, PO Box 1450 Alexandria, VA 22313-1450.

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April 16, 2004  
Date of Deposit

  
Cynthia B. Pacheco

In accordance with §1.97(b), this Information Disclosure Statement is being filed within three months of the filing date of the above-identified application, and therefore no fee is required.

In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the Patent and Trademark Office in one or more of the prior U.S. Application Serial No. 10/714,261, filed November 14, 2003, which claims the benefit of U.S. Provisional Patent Application Serial Nos. 60/427,654, filed November 18, 2002, 60/485,694, filed July 8, 2003, 60/495,048, filed August 13, 2003, and 60/496,483, filed August 19, 2003, by CAVALERI, et al. for which a claim for priority under 35 U.S.C. §120 has been made in the instant application. Accordingly, Applicants will provide duplicate copies in respect of the present case only if the Examiner so desires.

This statement should not be construed as a representation that more material information does not exist or that an exhaustive search of the relevant art has been made. Nor does this statement constitute an admission by Applicants or Applicants' agent that the information provided herein is necessarily prior art to Applicants' invention. Moreover, Applicants reserve the right to establish the patentability of the claimed invention over any of the listed documents should they be applied there-against as references. Please charge any deficiency or credit any overpayment to Deposit Account No. 50-2862.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: April 16, 2004

By *Diane K. Wong*  
Diane K. Wong  
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Form PTO-1449

# INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket No. 892,280-

Application No.: Not Yet Assigned

Applicant: CAVALERI et al.

Filing Date: Submitted herewith

Group Art Unit: Not Yet Assigned

Mailing Date: April 16, 2004

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	03/25/1980	4,195,079	Celmer et al.			
	2.	12/16/1980	4,239,751	Coronelli et al.			
	3.	09/17/1985	4,542,018	Borghi et al.			
	4.	04/28/1987	4,661,470	Malabarba et al.			
	5.	11/01/1988	4,782,042	Selva et al.			
	6.	09/19/1989	4,868,171	Selva et al.			
	7.	11/21/1989	4,882,313	Sitrin			
	8.	04/03/1990	4,914,187	Malabarba et al.			
	9.	06/19/1990	4,935,238	Selva et al.			
	10.	09/04/1990	4,954,483	Malabarba et al.			
	11.	07/09/1991	5,030,619	Hector			
	12.	11/12/1991	5,064,811	Borghi et al.			
	13.	02/25/1997	5,606,036	Hermann et al.			
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	21.	11/07/2000	6,143,739	Lociuro et al.			
	22.	04/17/2001	6,218,505	Panzone et al.			
	23.	05/07/2002	6,384,013	Burkhardt et al.			

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	24.	02/16/1983	EP 0 071 970	Europe				
	25.	11/30/1983	EP 0 095 154	Europe				
	26.	04/16/1986	EP 0 177 882	Europe				
	27.	12/10/1986	EP 0 204 179	Europe				
	28.	07/08/1987	EP 0 228 015	Europe				
	29.	10/14/1987	EP 0 240 609	Europe				
	30.	03/16/1988	EP 0 259 781	Europe				
	31.	02/01/1989	EP 0 301 785	Europe				
	32.	05/24/1989	EP 0 316 712	Europe				
	33.	07/04/1990	EP 0 376 041	Europe				
	34.	02/03/1993	EP 0 525 499	Europe				
	35.	10/15/1997	EP 0 801 075	Europe				
	36.	07/28/1999	EP 0 931 834	Europe				
	37.	12/21/1983	GB 2 121 401	Great Britain				
	38.	02/15/1984	GB 2 142 234	Great Britain				
	39.	02/01/1989	JP 1050900	Japan			Abstract	
	40.	04/21/1988	WO 88/02755	WIPO				
	41.	10/04/1990	WO 90/11300	WIPO				

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	42.	Abramson, M.A. and Sexton, D.J. (1999). "Nosocomial Methicillin-Resistant and Methicillin-Susceptible <i>Staphylococcus Aureus</i> Primary Bacteremia: At What Costs?" <i>Infect. Control Hosp. Epidemiol.</i> 20(6): 408-411.
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	44.	Ahrendt, K.A. et al. (2003). "Identification of Potent and Broad-Spectrum Antibiotics from SAR Studies of a Synthetic Vancomycin Analogue," <i>Bioorganic &amp; Medicinal Chemistry Letters</i> 13:1683-1686.	
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	51.	Arthur, M. and Courvalin, P. (1993). "Genetics and Mechanisms of Glycopeptide Resistance in Enterococci," <i>Antimicrobial Agents and Chemotherapy</i> 37(8):1563-1571.	
	52.	Author unknown. (2001). "Dalbavancin tested for soft tissue infections," located at < <a href="http://www.qxhealth.com/news_archive/cfm/search_details.cfm?sum_ID=8777">http://www.qxhealth.com/news_archive/cfm/search_details.cfm?sum_ID=8777</a> > last visited on September 8, 2003, one page.	
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<b>Form PTO-1449</b>  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <i>(Use several sheets if necessary)</i>	<b>Docket No. 892,280-</b>	<b>Application No.: Not Yet Assigned</b>
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	<b>Filing Date: Submitted herewith</b>	<b>Group Art Unit: Not Yet Assigned</b>
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60.	Cavaleri, M. et al. (2002). "Protein Binding of Dalbavancin Using Isothermal Titration Microcalorimetry," <i>42nd ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1385, pg. 18.
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62.	Chaix, C. et al. (1999). "Control of Endemic Methicillin-Resistant <i>Staphylococcus Aureus</i> ," <i>JAMA</i> 282(18):1745-1751.
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65.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. Abstract No. 52, pg. 53.
66.	Dorr, M.B. et al. (2002). "Rationale for Once Weekly Dosing of Dalbavancin, a New Semisynthetic Glycopeptide," <i>Abstracts of the IDSA 40th Annual Meeting</i> , October 24 - 27, 2002. <b>Poster No. 52</b> , one page.
67.	Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , Abstract No. P1224. Vol. 9(Supp. 1), p. 291.
68.	Dowell, J. et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment," <i>ECCMID: Clinical Microbiology and Infection</i> , <b>Poster No. P1224</b> , one page.
69.	Dowell, J.A. et al. (2002). "The Pharmacokinetics and Renal Excretion of Dalbavancin in Healthy Subjects," <i>42 ICAAC Abstracts</i> , San Diego, CA, September 27-30, 2002. Abstract No. A-1386, pg. - 18.
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72.	Ednie, L. et al. (2003). "Antistaphylococcal Activity of Dalbavancin Compared to Those of Six Other Agents," <i>43rd. Annual ICAAC</i> , Chicago, IL, September 14-17, 2003, <b>Poster #C1-1631</b> , one page.
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	75.	Ge, M. et al. (1999). "Vancomycin Derivatives That Inhibit Peptidoglycan Biosynthesis Without Binding D-Ala-D-Ala," <i>Science</i> 284:507-511.
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	77.	Goldstein, D. (May 10, 2001). "Versicor, Inc. Will Host Conference Call to Discuss Advanced Clinical Development Programs For Lead Antifungal and Antibiotic Products." Press Release, two pages.
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	81.	Goldstein, D. and Halsey, K. (May 21, 2002). "Versicor Announces Completion of Phase II Study of Once-Weekly Dalbavancin for Skin and Soft Tissue Infections." Press Release, three pages.
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	83.	Goldstein, D. et al. (December 17, 2001). "Versicor Announces Positive Phase I Data for Dalbavancin, Demonstrating Feasibility of Once-Weekly Dosing." Press Release, four pages.
	84.	Goldstein, D. et al. (September 5, 2002). "Versicor Announces Positive Phase 2 Study Results With Dalbavancin For Skin and Soft Tissue Infections." Press Release, three pages.
	85.	Goldstein, D. et al. (September 19, 2002). "Versicor Announces 24 Abstracts to be Presented at Annual ICAAC Meeting Next Week." Press Release, three pages.
	86.	Goldstein, D. et al. (October 23, 2002). "Versicor Announces Data Presentations Highlighting Advanced Product Candidates at IDSA Annual Meeting." Press Release, three pages.
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89.	Goldstein, E.J.C. et al. (2003). "In Vitro Activities of Dalbavancin and Nine Comparator Agents against Anaerobic Gram-Positive Species and Corynebacteria," <i>Antimicrob. Agents and Chemother.</i> 47(6): 1968-1971.
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91.	Griffin, J.H. (2003). "Multivalent Drug Design, Synthesis and In Vitro Analysis of an Array of Vancomycin Dimers," <i>JACS</i> 125:6517-6531.
92.	Hackbarth, C.J. et al. (1999). "In Vitro Activity of the Glycopeptide BI 397 Against <i>Staphylococcus aureus</i> and <i>Staphylococcus epidermidis</i> ," <i>39th Annual ICAAC</i> , San Francisco, CA. September 1999. Abstract No. 1283, pg. 332.
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99.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Linezolid (LN) Doses against Penicillin-Resistant Pneumococci (PRSP) in a Lobar Pneumonia (LP) Model in the Immunocompetent Rat (IR)," <i>41st. ICAAC Abstracts</i> , Chicago, IL, September 22-25, 2001. Abstract No. B-989, p. 54.
100.	Jabes, D. et al. (December, 2000). " <i>In vitro</i> and <i>in vivo</i> Bactericidal Activity of the New Glycopeptide BI 397 and Correlations with Drug Concentrations," BioSearch Italia, S.P.A., San Antonio, December 2000, <b>Poster No. F5</b> , one page.
101.	Jabes, D. et al. (2001). "Efficacy of a Single Dalbavancin (DA) Dose Compared with Multiple Vancomycin (VA) Doses against MRSA in the Rat Pouch Model of Infection," <i>41st. ICAAC Abstracts</i> , Chicago, IL. September 22 - 25, 2001. Abstract No. B-1654, pg. 68.
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	103.	Jabes, D. et al. (2003). "Efficacy of Dalbavancin Compared with Vancomycin and Linezolid in the Rat Granuloma Pouch Model of Staphylococcal Infection," <i>Symposium on Surgical Infections</i> , Como, Italy <b>Poster No. P1</b> , one page.	
	104.	Jain, R.K. (2003). "D-Ala-D-Lac Binding Is Not Required for the High Activity of Vancomycin Dimers Against Vancomycin Resistant Enterococci," <i>JACS</i> 125:8740-8741.	
	105.	Jones, R. N. et al. (2001). "Activity and Spectrum Evaluation of Dalbavancin (V-Glycopeptide and BI397), A Novel "Glycopeptide" Class Antimicrobial," <i>41st ICAAC Abstracts</i> , Chicago, IL. September 22-25, 2001, Abstract No. 2276, pg. 200.	
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